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Proposed Re-evaluation Decision PRVD2017-14

Aminoethoxyvinylglycine Hydrochloride and Its Associated End-use Products

Consultation Document

(publié aussi en français)

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of the pesticide products containing aminoethoxyvinylglycine hydrochloride, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing aminoethoxyvinylglycine hydrochloride for sale and use in Canada.

An evaluation of available scientific information has found that products containing aminoethoxyvinylglycine hydrochloride do not present unacceptable risks to human health or the environment when they are used according to label directions. As a requirement of the continued registration of aminoethoxyvinylglycine hydrochloride uses, label amendments are proposed to be included on the product label.

This proposal affects all pesticide products containing aminoethoxyvinylglycine hydrochloride registered in Canada.

This Proposed Re-evaluation Decision (PRVD) is a consultation document[1] that summarizes the science evaluation for aminoethoxyvinylglycine hydrochloride and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The 'Overview' describes the regulatory process and key points of the re-evaluation, while the 'Science Evaluation' provides additional technical information on the assessment of aminoethoxyvinylglycine hydrochloride.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA pesticide re-evaluation program considers potential risks, as well as value of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What is Aminoethoxyvinylglycine Hydrochloride?

Aminoethoxyvinylglycine hydrochloride is a plant growth regulator for use in apples. It is used as a harvest management tool to control fruit drop and delay maturity which allows growers to better schedule harvesting and avoid losses from dropped apples.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Aminoethoxyvinylglycine Hydrochloride Affect Human Health?

Aminoethoxyvinylglycine hydrochloride is unlikely to affect your health when used according to the label directions.

Potential exposure to aminoethoxyvinylglycine hydrochloride may occur by applying the end-use product, entering treated fields or consuming food and water. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

Risk in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is not of concern

Aminoethoxyvinylglycine hydrochloride is not registered for residential use in Canada. Therefore residential exposure is not expected.

Occupational Risks From Handling Products Containing Aminoethoxyvinylglycine Hydrochloride

Occupational risks are not of concern when products containing aminoethoxyvinylglycine hydrochloride are used according to the label directions, which include protective measures.

Risk from occupational exposure to workers mixing, loading and applying the end-use product, as well as to workers re-entering treated fields, is not of concern when aminoethoxyvinylglycine hydrochloride is used according to the label directions.

Exposure to bystanders is not expected to result in health risks of concern when the end-use product is used according to label directions.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary exposure to aminoethoxyvinylglycine hydrochloride through consumption of food and drinking water is not of concern.

Environmental Considerations

What Happens When Aminoethoxyvinylglycine Hydrochloride is Introduced into the Environment?

When used according to the revised label directions, aminoethoxyvinylglycine hydrochloride is not expected to pose risks of concern to the environment.

Aminoethoxyvinylglycine hydrochloride enters the environment when it is applied as a plant growth regulator to apple trees. Aminoethoxyvinylglycine hydrochloride breaks down quickly in the presence of microbes, and is not expected to build-up in soil and water. The breakdown products of aminoethoxyvinylglycine hydrochloride are not expected to persist in the environment. Aminoethoxyvinylglycine hydrochloride has low mobility in soil and is not expected to move through the soil and reach groundwater. It is not expected to enter the atmosphere and travel long distances from where it was applied. Aminoethoxyvinylglycine hydrochloride is not expected to accumulate in the tissues of organisms.

Aminoethoxyvinylglycine hydrochloride does not present a risk of concern to terrestrial plants, wild mammals, birds, bees, invertebrates, fish or aquatic invertebrates. However, exposure to aminoethoxyvinylglycine hydrochloride can affect aquatic plant and algae species if they are exposed to high enough levels. To protect non-target organisms in water from spray drift, updated aquatic buffer zones are proposed.

Value Considerations

What is the Value of aminoethoxyvinylglycine hydrochloride

Aminoethoxyvinylglycine hydrochloride has value as a harvest management tool. The active is one of two pesticides currently in use for the control of pre-harvest drop in apples.

Measures to Minimize Risk

Labels of registered pesticide products include instructions for use. The directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of aminoethoxyvinylglycine hydrochloride, the PMRA is proposing updated aquatic buffer zones for the product label.

What Additional Scientific Information is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on aminoethoxyvinylglycine hydrochloride, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on aminoethoxyvinylglycine hydrochloride. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Aminoethoxyvinylglycine hydrochloride is a plant growth regulator which inhibits the biosynthesis of ethylene in plants.

The registrant has indicated support for the re-evaluation of all products containing the active ingredient. Currently registered products containing aminoethoxyvinylglycine hydrochloride are listed in Appendix I.

2.0 Use Description of Aminoethoxyvinylglycine Hydrochloride

Aminoethoxyvinylglycine hydrochloride, also referred as aviglycine hydrochloride, was first registered in Canada in 1998. Aminoethoxyvinylglycine hydrochloride is a plant growth regulator which inhibits the biosynthesis of ethylene in plants by interfering with the functioning of the enzyme, 1-animocyclopro-panecarboxylate (ACC) synthase. Inhibition of ethylene production results in prevention of pre-harvest fruit abscission (fruit detachment), and may also delay fruit maturity and increase fruit firmness. Aminoethoxyvinylglycine hydrochloride is applied to apples once per season, by ground application using airblast sprayer (applied alone or with a silicone surfactant), 4 weeks before the anticipated beginning of the normal harvest period at 125 g a.i. per hectare.

3.0 The Technical Grade Active Ingredient and Its Properties

3.1 Identity of the Technical Grade Active Ingredient

Common Name: AVIGLYCINE HYDROCHLORIDE

Function: Plant growth regulator

Chemical Name:

- International Union of Pure and Applied Chemistry (IUPAC):

  (E)-L-2-[2-(2-AMINOETHOXY)VINYL] GLYCINE HYDROCHLORIDE

- Chemical Abstracts Service (CAS):

  (2S,3E)-2-AMINO-4-(2-AMINOETHOXY)-3-BUTENOIC ACID MONOHYDROCHLORIDE

CAS Registry Number: 55720-26-8

Registration Number: 25608

3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Ultraviolet/visible spectrum	No absorption peaks between 200-600 nm
Solubility in water at room temperature	39.6-47.2 g/100 mL
Octanol/water partition coefficient (log K_{ow})	-3.98
Vapour pressure	Not applicable
Dissociation constant (pK_a) at 20 °C	2.84 ∀ 0.3 8.81 ∀ 0.01 9.95 ∀ 0.01

4.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much greater) than levels to which humans are normally exposed when pesticide products are used according to label directions. Based on the registered use pattern, exposure to aminoethoxyvinylglycine hydrochloride may occur through consuming food and drinking water, working as a mixer/loader/applicator, or by entering treated sites.

When assessing health risks, the PMRA considers two key factors: the dose levels at which no adverse health effects occur (that is, the No Observed Adverse Effect Level – NOAEL), and the dose levels to which people may be exposed. The NOAELs used to assess risks are established to protect the most sensitive human population, for example, children and nursing mothers. As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

4.1 Toxicology Summary

The database for aminoethoxyvinylglycine hydrochloride is considered complete. Aminoethoxyvinylglycine hydrochloride is of low acute toxicity via oral and dermal routes and is slightly toxic via the inhalation route. It is minimally irritating to eyes and skin.

Absorption and excretion of single oral dose of the active were rapid in animals. Residues of the active declined rapidly in animal tissues. No treatment related effects were noted in the short-term dermal study. In subchronic and chronic studies, decreases in body weight, body weight gain and food consumption and/or food efficiency were observed in mice, rats and dogs. There was no evidence of genotoxicity or carcinogenicity observed.

There was no evidence of malformations in the developmental toxicity studies in rats and rabbits. In the reproductive toxicity study, offspring effects occurred at a maternally toxic dose consisting of increased stillbirths, low birth weight, increased total litter loss, decreased litter size and pup care.

The PMRA toxicology endpoints used in human health risk assessment are summarized in Appendix II.

4.2 *Pest Control Products Act* Hazard Characterization

The *Pest Control Products Act* factor was previously assessed for aminoethoxyvinylglycine hydrochloride and was reduced to 1-fold.

4.3 Occupational Exposure and Risk

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a Margin of Exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to aminoethoxyvinylglycine hydrochloride through mixing, loading or applying the product using an airblast sprayer or when entering a treated site to conduct activities such as scouting and/or handling treated crops.

4.3.1 Dermal Absorption

A dermal absorption factor of 1.6% was assumed based on an in vivo dermal absorption study in rats.

4.3.2 Mixer/Loader/Applicator Exposure and Risk

Mixer/loader/applicator exposure to aminoethoxyvinylglycine hydrochloride is expected to be mainly via dermal and inhalation routes over a short-term duration (applied once per season during narrow seasonal application window). Mixer/loader/applicator exposure was estimated based on open-cab airblast application with current label protective equipment (coveralls over single layer and chemical resistant gloves) and standard assumptions. The combined short-term dermal and inhalation MOEs are above the target MOE of 100 for all assessed scenarios. On this basis, the mixer/loader/applicator exposure is not of concern when the current label directions are followed. No additional risk mitigation measures are proposed.

4.3.3 Postapplication Exposure and Risk

For workers entering treated fields to conduct post-application activities, dermal exposure is considered to be the primary route of exposure. Aminoethoxyvinylglycine hydrochloride is non-volatile and meets the North American Free Trade Agreement (NAFTA) criterion for an

inhalation waiver based on low volatility due to a vapour pressure of less than 7.5×10^{-4} mm Hg (NAFTA, 1999). Thus, inhalation exposure is considered minimal and is not expected to be of concern for post-application activities.

Exposure was estimated based on peak dislodgeable foliar residues assuming an application rate of 125 g a.i./ha and activity specific transfer coefficients for various applicable re-entry activities. Postapplication exposure is not of concern on the day of application for all assessed activities. The current label includes the default restricted-entry interval (REI) of 12 hours. No additional risk mitigation measures are proposed.

4.4 Non-Occupational Exposure and Risk:

4.4.1 Residential and Bystander Exposure and Risk

Aminoethoxyvinylglycine hydrochloride is not registered for residential use in Canada. Therefore residential exposure is not expected.

The use of aminoethoxyvinylglycine hydrochloride could result in potential bystander exposure through spray drift. Bystander exposure is mitigated by the standard spray drift advisory label statement currently included on the end-use product label. No additional risk mitigation measures are proposed.

4.4.2 Dietary Exposure and Risk

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in meat and milk, may be ingested with the daily diet (food and drinking water).

These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

A toxicity endpoint attributable to a single dose was not identified. Therefore, the establishment of an acute reference dose and acute risk assessment was not required.

Chronic dietary exposure in food was calculated by using combined maximum residues from field trial data for the parent and the N-acetyl metabolite as well as assuming Canadian maximum residue limit (MRL) and American tolerance, residue levels. In water, the estimated concentrations in potential drinking water sources (groundwater and surface water) were generated using modeling based on conservative assumptions with respect to environmental fate, application rate and timing.

The expected intake of residues was then compared to the ADI, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the calculated intake of residues from all food sources (including water) is less than the ADI, then chronic dietary exposure is not of concern.

The ADI for aminoethoxyvinylglycine hydrochloride was determined to be 0.004 mg/kg bw/day based on a NOAEL of 0.4 mg/kg bw/day and a composite assessment factor of 100. The refined chronic dietary exposure from food only ranged from 1.2% to 18.3% of the ADI to all population subgroups. The refined aggregate chronic dietary exposure from food and drinking water, assuming a modeled concentration of 0.028 µg a.i./L in drinking water, ranged from 1.2% to 18.4% of the ADI for all population subgroups. Thus, the chronic dietary exposure of aminoethoxyvinylglycine hydrochloride is not of concern. No additional risk mitigation measures are proposed.

4.5 Aggregate Exposure and Risk

For aminoethoxyvinylglycine hydrochloride, residential exposure is not expected; therefore the aggregate exposure is limited to food and drinking water only. The aggregate dietary exposure from food and drinking water is considered acceptable and is not of concern for all population subgroups (refer to Section 4.4.2).

4.6 Cumulative Exposure and Risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that aminoethoxyvinylglycine hydrochloride shares a common mechanism of toxicity with other pest control products. Therefore there is no requirement for a cumulative assessment at this time.

4.7 Maximum Residue Limits

The *Food and Drug Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that is at or below the established MRL does not pose an unacceptable health risk.

A Canadian MRL for aminoethoxyvinylglycine hydrochloride is currently specified for apples. For all other agricultural commodities, residues must not exceed 0.1 ppm as per subsection B.15.002(1) of the *Food and Drug Regulations*.

5.0 Environment

Aminoethoxyvinylglycine hydrochloride enters the environment when applied as a plant growth regulator to apple trees. Non-target terrestrial and aquatic habitats may be exposed to the chemical as a result of spray drift or runoff.

5.1 Environmental Fate

The physical and chemical properties of aminoethoxyvinylglycine hydrochloride are summarized in the Section 3.2. Aminoethoxyvinylglycine hydrochloride is soluble in water. Under acidic, neutral or basic pH conditions, aminoethoxyvinylglycine hydrochloride is not expected to hydrolyze, nor is it likely to phototransform in water and on soil. It is not expected to volatilize from moist soil or water.

Biotransformation is expected to be a major route of transformation for aminoethoxyvinylglycine hydrochloride. Results from a biotransformation study indicate that aminoethoxyvinylglycine hydrochloride is non-persistent in aerobic soil with a half-life of 1.7-4.7 days depending on soil type. There were three transformation products formed, of which two were major transient products and the third was a minor product.

Although aminoethoxyvinylglycine hydrochloride is soluble in water, laboratory studies have indicated that it is immobile in sandy loam and loam soils (K_{oc} = 7495 and 7386 ml/g, respectively) and of low mobility in humic sand and low humic sand soils (K_{oc} = 561 and 1028 ml/g, respectively). Thus, there is low potential for leaching to groundwater under field conditions.

Aminoethoxyvinylglycine hydrochloride is not persistent in water-sediment systems, with a half-life of 4.3 days. One major transient transformation product and one minor transformation product were formed in the water-sediment biotransformation studies. In aquatic environments, aminoethoxyvinylglycine hydrochloride is expected to partition into sediment.

Based on its log K_{ow} value, aminoethoxyvinylglycine hydrochloride has low potential for bioaccumulation

5.2 Environmental Exposure and Risk Assessment

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur.

Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or

groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level). Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints.

A summary of effects of aminoethoxyvinylglycine hydrochloride on terrestrial and aquatic organisms is presented in Appendix III.

Expected Environmental Concentrations (EECs) of aminoethoxyvinylglycine hydrochloride in various environmental compartments were calculated assuming one application per season based on the maximum Canadian label rate of 125 g ai/ha.

5.2.1 Aquatic Species

The screening level assessment indicated that aminoethoxyvinylglycine hydrochloride poses a negligible risk to freshwater invertebrates and fish (RQ = 0.0003) and diatoms (RQ = 0.056). The LOC was exceeded for aquatic vascular plants (RQ = 1.67) and algae (RQs = 1.19–69.5). To minimize the exposure to aquatic organisms, spray buffer zones of up to three meters is proposed. The proposed updated buffer zones are listed in Appendix IV.

5.2.2 Terrestrial Species

The screening level assessment indicated no risks of concern to terrestrial species including birds, mammals and plants. In addition, based on the timing of application (i.e., late in the growing season) and the low toxicity to honey bees, predators and parasites, the use of aminoethoxyvinylglycine hydrochloride is not expected to pose a risk of concern to honey bees or other beneficial arthropods. Terrestrial buffer zones are not required. No additional risk mitigation measures are proposed.

6.0 Value

Aminoethoxyvinylglycine hydrochloride has value as a harvest management tool to control fruit drop and to delay maturity that allows growers to better schedule the harvest period and prevents loss from dropped apples. Aminoethoxyvinylglycine controls the maturation rates of later apple

picks but will not delay the start of harvest. It does not belong to a resistance management group. The active is one of two pesticides currently in use for the control of pre-harvest drop in apples. Aminoethoxyvinylglycine hydrochloride can also affect the normal ripening of the fruits, while the other pesticide does not.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy (TSMP) Considerations

Based on the available information, aminoethoxyvinylglycine hydrochloride does not meet TSMP Track 1 criteria. The active ingredient is not persistent in the environment and is not expected to bioaccumulate. Aminoethoxyvinylglycine hydrochloride does not form any transformation products that meet all Track 1 criteria.

The use of Aminoethoxyvinylglycine hydrochloride is not expected to result in the entry of TSMP Track-1 substances into the environment.

7.2 Contaminants of Health or Environmental Concern

During the re-evaluation of aminoethoxyvinylglycine hydrochloride, contaminants in the technical were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3] The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

Aminoethoxyvinylglycine hydrochloride end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

8.0 Incident Reports

As of 15 June 2017, one environmental incident has been received by the PMRA; no human incidents have been reported to the Agency. The environmental incident occurred after a fire occurred at a chemical distribution warehouse. The water used to douse the fire entered a nearby creek, and fish kill was reported. There were several products being stored at the warehouse at the time of the fire. The active ingredient aminoethoxyvinylglycine hydrochloride was considered unlikely to have been the cause of the fish kill.

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[3] *Canada Gazette, Part II*, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643; *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and to the order amending this list in the Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. Part 1 *Formulants of Health or Environmental Concern*, Part 2 *Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions* and Part 3 *Contaminants of Health or Environmental Concern*.

As of 5 October 2015, the USEPA had received 16 aminoethoxyvinylglycine hydrochloride environment incident reports. In all cases, trees were damaged after having been treated directly with a product containing aminoethoxyvinylglycine.

Based on the review of the incidents reported to the PMRA, no environmental risks of concern have been identified.

9.0 Organisation for Economic Co-operation and Development Regulatory Status of Aminoethoxyvinylglycine Hydrochloride

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experience and seek solutions to common issues.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

Aminoethoxyvinylglycine hydrochloride is currently acceptable for use in other OECD member countries, including the United States, Australia and New Zealand. As of 31 May 2017, no decision by an OECD member country to prohibit all uses of the active ingredient for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

The PMRA has determined that products containing aminoethoxyvinylglycine hydrochloride for sale and use in Canada are acceptable for continued registration with the proposed label amendments in Appendix IV.

List of Abbreviations

ACC	animocyclopropanecarboxylate
ADI	acceptable daily intake
AVG	aviglycine hydrochloride
bw	body weight
CAF	composite assessment factor
CAS	Chemical Abstracts Service
EC_{25}	25% effective concentration
EC_{50}	median effective concentration
EbC_{50}	median reduction concentration in growth rate [mg/L]
EEC	estimated environmental concentration
ErC_{50}	median reduction concentration in biomass growth [mg/L]
EUP	end-use product
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
Kg	kilogram
K_{ow}	the *n*-octanol–water partition coefficient
L	liter
LC_{50}	median lethal concentration [mg a.i./kg diet or mg a.i./L]
LD_{50}	median lethal dose [mg a.i./kg bw]
mg	milligram
MOE	margin of exposure
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect
NOEC	no observable effect concentration [mg a.i./kg diet or mg a.i./L]
OECD	Organisation for Economic Co-operation and Development
pK_a	- log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
REI	restricted-entry interval
RQ	risk quotient
TSMP	Toxic Substances Management Policy

Appendix I Registered Products Containing Aminoethoxyvinylglycine Hydrochloride as of 31 May 2017.

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
25608	Technical	Valent BioSciences Corporation	ReTain Technical Powder	Soluble powder	86.0%
25609	Commercial	Valent BioSciences Corporation	ReTain Plant Growth Regulator	Soluble powder	15.0%

Appendix II PMRA Toxicology Endpoints for Use in Health Risk Assessments for Aminoethoxyvinylglycine Hydrochloride.

Exposure Scenario	Dose[1] (mg/kg bw/day)	Study	CAF or Target MOE[2]
Chronic Dietary	NOAEL = 0.4	Rabbit Developmental Toxicity. Based on decreased body weights, body weight gains and food consumption in adults as well as decrease of female fetal weights.	100
	ADI = 0.004 mg/kg bw/day		
Acute Dietary.	An appropriate toxicity endpoint attributable to a single dose was not identified. Therefore, an acute reference dose was not established		
Short -Term Dermal and Inhalation[3]	NOAEL = 0.4	Rabbit Developmental Toxicity. Based on decreased body weights, body weight gains and food consumption in adults as well as decrease of female fetal weights.	100
No evidence of carcinogenicity			

1 NOAEL = no observed adverse effect level; ADI = acceptable daily intake.

2 CAF = composite assessment factor; MOE = margin of exposure.

3 For route to route extrapolation, a dermal absorption factor of 1.6% was assumed.

Appendix III Summary of Effects of Aminoethoxyvinylglycine hydrochloride on Terrestrial and Aquatic Organisms.

Group	Organism	Exposure	Endpoint	Degree of Toxicity
Aquatic Species				
Invertebrate	*Daphnia magna*	48 hour	LC_{50}: >135 mg ai/L NOEC (mortality): 135 mg ai/L	Practically non-toxic
Fish	*Onchorynchus mykiss*	96 hour	LC_{50}: >139 mg ai/L NOEC (mortality): 139 mg ai/L	Practically non-toxic
Algae	*Selenastrum capricornutum* (15% a.i)	72 hour	$EbC_{50\ (biomass)}$: 0.0298 mg a.i./L $NOEC_{\ (biomass)}$: 0.0137 mg a.i./L $ErC_{50\ (growth\ rate)}$: 0.0474 mg a.i./L $NOEC_{\ (growth\ rate)}$: 0.0137 mg a.i./L	----
	Selenastrum capricornutum (82% a.i.)	72 hour	$EbC_{50\ (biomass)}$: 0.021 mg ai/L $NOEC_{\ (biomass)}$: 0.0059 mg ai/L $ErC_{50\ (growth\ rate)}$: 0.0535 mg ai/L $NOEC_{\ (growth\ rate)}$: 0.0133 mg ai/L	-----
	Anaebaena sp. (82% a.i.)	72 hour	$EbC_{50\ (biomass)}$: 0.0061 mg ai/L $NOEC_{\ (biomass)}$: 0.0035 mg ai/L $ErC_{50\ (growth\ rate)}$: 0.021 mg ai/L $NOEC_{\ (growth\ rate)}$: 0.0035 mg ai/L	----
Diatom	*Naviculla pelliculosa* (82% a.i.)	72 hour	$EbC_{50\ (biomass)}$: 4.34 mg ai/L $NOEC_{\ (biomass)}$: 0.741 mg ai/L $ErC_{50\ (growth\ rate)}$: 23.3 mg ai/L $NOEC_{\ (growth\ rate)}$: 0.741 mg ai/L	----
Vascular plants	*Lemna gibba*	7-day	3 day EC_{50}: 0.102 mg ai/L $NOEC_{\ (frond\ number)}$: 0.025 mg ai/L	-----
Terrestrial Species				
Birds	*Colinus virginianus*	14 day acute (80.6% a.i.)	LD_{50}: 121 mg ai/kg bw NOEL (mortality + bw): 15.62 mg ai/kg bw	Moderately toxic
		8 day dietary (80.6% a.i.)	LC_{50}: 230 mg ai/kg bw NOEC (mortality): 130 mg ai/kg bw NOEC (↓bw gain):47 mg ai/kg bw	Highly toxic
		Reproduction (88% a.i.)	$NOEC_{\ (food\ consumption\ +\ bw)}$: 140 mg ai/kg diet NOEC (% bw): 19 mg ai/kg diet $NOEC_{\ (reproduction)}$: 49 mg ai/kg diet	----
	Anas platyrhynchos	11 day dietary	LD_{50}: 459 mg ai/kg bw NOEC (mortality):94.2 mg ai/kg bw	Highly toxic
Mammals	rats	acute	LD_{50}: 5513 mg ai/kg bw LOEL: 4030 mg ai/kg bw	non-toxic
		3-month dietary	NOEL: 4.81 mg ai/kg diet	-----
Bees	*Apis mellifera* (82% a.i.)	48 hour contact and oral	LD_{50}: >100 Φg/bee NOEL/C: 100 Φg/bee	Non-toxic
Predators + Parasites	*Aphidius rhopalosiphi*	48 hours	LC_{50}: >500 g ha 0% mortality at 500 g/ha	Harmless
		11 days	$NOEC_{\ (fecundity)}$: 125 g ha	
	Chrysoperla	21 days	LC_{50}: >500 g ha	Harmless

Group	Organism	Exposure	Endpoint	Degree of Toxicity
	carnea (15% a.i.)		0% mortality at 500 g/ha NOEC $_{(reproduction)}$: 500 g ha	
	Poecilus cupreus (15% a.i.)	14 days	LC_{50}: >500 g ha NOEC $_{(food\ consumption)}$: 500 g ha	Harmless
Terrestrial plants	seedling emergence and vegetative vigour	14 days	EC_{25}: >124 g ai/ha NOEC: 124 g ai/ha	---

Appendix IV Label Amendments for Commercial Class End-Use Products Containing Aminoethoxyvinylglycine hydrochloride

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

Add to ENVIRONMENTAL PRECAUTIONS:

TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

Add to DIRECTIONS FOR USE:

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Airblast sprayer	Apples	Late growth stage	3	1	3	1

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator found on the Drift Mitigation page of the Pesticides and Pest Management portion of the Canada.ca web site.

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